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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,735	05/18/2000	Lieven DeVeylder	1187-2 CIP	1507
28249	7590	04/21/2006	EXAMINER	
DILWORTH & BARRESE, LLP 333 EARLE OVINGTON BLVD. UNIONDALE, NY 11553			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/574,735	DEVEYLDER ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 January 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2,5,7-11,14,17,21,24,25,27,30,36-41,43-45,47-50,52-57 and 60-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2,5,7-11,14,17,21,24,25,27,30,36-41,43-45,47-50,52-57 and 60-92 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed January 13, 2006 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 16, 2005 has been entered.

Claims 1, 3-4, 6, 12-13, 15-16, 18-20, 22-23, 26, 28-29, 31-35, 42, 46, 51 and 58-59 are cancelled.

Claims 2, 5, 7, 11, 14, 17, 21, 25, 27, 30, 36, 54-55 and 89-90 are currently amended.

Claims 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50, 52-57 and 60-92 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 60-92 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention, for the reasons of record. This is a new matter rejection.

Claims 60-86 and 89-92 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record. This is a written description rejection.

Applicants' arguments filed November 16, 2005 have been fully considered but they are not fully persuasive with respect to all of the rejected claims.

Applicants point out that in response to the rejection and in order to advance prosecution in this case, Applicants have amended claims 2, 5, 7, 11, 14, 17, 21, 25, 27, 30, 36, 54 and 55 to recite the percent identities exemplified by different plants as set forth in Table 2 of the specification; i.e. as presently amended, these claims recite the exact sequence identities disclosed by the specification for nine different plant ICKS.
(reply pages 22-24)

The Examiner acknowledges the amendment of claims 2, 5, 7, 11, 14, 17, 21, 25, 27, 30, 36, 54 and 55 to recite the exact percent identities exemplified by different plants as set forth in Table 2 of the specification, and the written description rejection is withdrawn with respect to these claims. The rejection is maintained, however, with respect to the remaining claims, as the disclosed species are not representative of the claimed genus, wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any

position therein, and wherein one or both of the sequences set forth in SEQ ID NOS: 37 and 39 has one unspecified amino acid substitution at any position therein. The rejection is also maintained with respect to the remaining claims as CKIs comprising the consensus sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein do not find support in the specification as filed and thus constitute new matter, and CKIs further comprising the consensus sequences set forth in SEQ ID NO:37, SEQ ID NO:38, and SEQ ID NO:39 wherein one or both of the sequences set forth in SEQ ID NOS: 37 and 39 has one unspecified amino acid substitution at any position therein do not find support in the specification as filed and thus constitute new matter.

Applicants submit that it is certainly not inappropriate to mention *Ex parte Yuejin Sun*, since the previous paper was an amendment, and not an appeal brief, and since referencing this case as well as providing a copy as Exhibit A was done as a courtesy in order to direct the Examiner to a case in the same field of technology, where one particular panel of the Board of Appeals and Patent Interferences might not agree with the position the Examiner has taken in the present application. (reply page 26)

The Examiner maintains that Applicants' reliance on *Ex parte Yuejin Sun* is inappropriate, since the opinion in support of that decision was not written for publication and is not binding precedent of the Board. The Examiner also maintains that *Ex parte Yuejin Sun* is not in the same field of technology as the instant case. The sequences at issue in *Ex parte Yuejin Sun* encode wee1 protein kinase polypeptides, whereas the

sequences at issue in the instant case encode cyclin-dependent kinase inhibitor polypeptides. Further, both the structural and the functional parameters used to define the genus of sequences at issue in *Ex parte Yuejin Sun* differ from the structural and functional parameters used to define the genus of sequences at issue here.

Applicants also do not agree with the Examiner's characterization that one skilled in the art would not know on the basis of the disclosure which of the 20 different amino acid residues would occupy which of the eight of ten available positions in each of the recited motifs that plant CKIs comprise. Applicants maintain that a more accurate characterization has been provided many times by Applicants during prosecution of this application: one skilled in the art, having the present specification in hand at the time the application was first filed, would have reasonably understood that the plant CKIs listed in Table 2 and comprising the consensus sequences also set forth in Table 2 as SEQ ID NOs:34-39, often have an amino acid substitution in one or more of these sequences, and that thus the substitution would only occur in one position and would not be an undeterminable substitution, but a very well defined one, one out of a possible twenty known amino acids.

The Examiner reiterates that one skilled in the art would not know on the basis of the disclosure which of the 20 different amino acid residues would occupy which of the eight of ten available positions in each of the recited motifs that plant CKIs comprise. The Examiner maintains that the understanding by one skilled in the art that the plant CKIs listed in Table 2 often have an amino acid substitution in one or more of their consensus sequences does not lead to the conclusion that the substitution would only

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occur in one position, as the plant CKIs listed in Table 2 do not have an amino acid substitution in one or more of their consensus sequences in only one position. The Examiner also maintains that the understanding by one skilled in the art that there are twenty known amino acids that may be substituted for each other does not lead to the conclusion that the substitution would not be an undeterminable substitution, as the twenty known amino acids are not necessarily interchangeable at a particular location in a particular amino acid sequence.

Applicants additionally maintain that the Examiner has erred by dismissing the declaration of Dr. Bergounioux without an adequate explanation of how the declaration failed to overcome a *prima facie* case that the pending claims are not supported by the written description. In this regard Applicants maintain that the fact that a sequence was published after the filing date of the present invention, does not take away from the declarant's relying on the written description of the present application in identifying that sequence and using the same in the presently claimed method, or from the fact that in relying on the written description in identifying this later-published sequence, the declarant reasonably believed that the inventors of the present application invented i.e., had possession of the subject matter later claimed by them (reply page 27)

The Examiner reiterates that sequences described after the filing date of the instant application (May 18, 2000) cannot be used to support a description of the claimed sequences. Further, the tobacco plant CKI NtKIS1a referred to in the declaration of Dr. Bergounioux does not support the description of the plant CKIs recited in the claims because the tobacco plant CKI NtKIS1a does not comprise the consensus sequences set

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forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein, and because the tobacco plant CKI NtKIS1a does not further comprise the consensus sequences set forth in SEQ ID NO:37, SEQ ID NO:38, and SEQ ID NO:39 wherein one or both of the sequences set forth in SEQ ID NOS: 37 and 39 has one unspecified amino acid substitution at any position therein. According to paragraph 7 of the declaration of Dr. Bergounioux (3/29/2005), the tobacco CKI, NtKIS1a, comprises a first sequence motif which is identical to the sequence set forth in SEQ ID NO:34, a second sequence motif comparable but not identical to the consensus sequence set forth in SEQ ID NO:35 (the second amino acid of SEQ ID NO:35, L, substituted with S in the tobacco CKI NtKIS1a), and a third sequence motif comparable but not identical to the consensus sequence set forth in SEQ ID NO:36 (the last amino acid of SEQ ID NO:36, E, substituted with Q in the tobacco CKI NtKIS1a).

Applicants also refer again to *In re Hogan*, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977), and maintain that while it is true that a later dated disclosure cannot supplement an insufficient disclosure in a prior dated application, the use of later publications (in this case, the later disclosures of rice CKI ICK2 submitted as part of the van Camp Rule 132 declaration and the later disclosure of tobacco CKI Kis1a a as part of the Bergounioux Rule 132 declaration) as evidence of the state of the art existing on the filing date of the application is appropriate. Applicants additionally maintain that the declaration of Dr. Bergounioux goes to the matter of what a reasonable skilled artisan

believed the inventors had in their possession as of the filing date of the present application, as evidenced by a skilled artisan 's reasonable reliance thereon, and that the post-filing date CKI sequence provided by Dr. Bergounioux evidences the reasonableness of her belief and reliance.

The Examiner maintains that Applicants' reliance on *In re Hogan* is inapposite to the outstanding rejection, as none of the claims at issue in *In re Hogan* were rejected under 35 USC 112, first paragraph, for inadequate written description. The Examiner also maintains that neither the tobacco plant CKI NtKIS1a nor the rice CKI ICK2 support the description of the plant CKIs recited in the claims, because neither the tobacco plant CKI NtKIS1a nor the rice CKI ICK2 comprise the consensus sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein, and neither the tobacco plant CKI NtKIS1a nor the rice CKI ICK2 further comprise the consensus sequences set forth in SEQ ID NO:37, SEQ ID NO:38, and SEQ ID NO:39 wherein one or both of the sequences set forth in SEQ ID NOS: 37 and 39 has one unspecified amino acid substitution at any position therein. The Examiner additionally maintains that what a reasonable skilled artisan believed the inventors had in their possession as of the filing date of the present application is not in itself sufficient to satisfy the written description requirement. See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1617:

Application of the written description requirement, however, is not subsumed by the "possession" inquiry. A showing of "possession" is ancillary to the *statutory* mandate that "[t]he specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. After all, as

indicated above, one can show possession of an invention by means of an affidavit or declaration during prosecution, as one does in an interference or when one files an affidavit under 37 C.F.R. § 1.131 to antedate a reference. However, such a showing of possession alone does not cure the lack of a written description in the specification, as required by statute.

Applicants further point to *In re Alton* 76 F3d 1 168, 1 175, 37 USPQ 2d 1578, 1583 (Fed Cir. 1996), where after a claim was first rejected under section 112, first paragraph, the applicant submitted evidence to rebut the rejection in the form of a declaration. This declaration set forth facts which supported the position that one of ordinary skill in the art would have understood the inventor (Alton) to be in possession of the claimed subject matter as of the relevant date. The Court of Appeals for the Federal Circuit held the Examiner in error for several reasons, most relevant to the issues in the present application was that the Wall declaration addressed why the claimed subject matter, although not identical to the analog described in the specification, was in Alton's possession, because the Wall declaration explained why one of ordinary skill in the art would have realized that Alton had possession of one particular analog. Applicants maintain that in the instant case the Examiner has failed to articulate adequate reasons to rebut the Bergounioux declaration with respect to the written description rejection. In particular, Applicants maintain that the Examiner has failed to address Dr. Bergounioux's statements at paragraphs 9 and 10. (reply pages 29-31)

With respect to Dr. Bergounioux assertions at paragraphs 9 and 10 that one skilled in the art would recognize that even if the consensus sequences vary somewhat from plant to plant, a motif in a plant having about 70% identity (or one amino acid substitution) to the consensus sequences set forth in Table 2 (SEQ ID NOs:34-39), would

be reasonably expected to function in the claimed invention with predictable results, as shown in the publication provided at Exhibit B with the results obtained from transformed 35S::NtKIS1a plants, the Examiner reiterates that the tobacco plant CKI NtKIS1a referred to in the declaration of Dr. Bergounioux does not support the description of the plant CKIs recited in the claims because the tobacco plant CKI NtKIS1a does not comprise the consensus sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein, and because the tobacco plant CKI NtKIS1a does not further comprise the consensus sequences set forth in SEQ ID NO:37, SEQ ID NO:38, and SEQ ID NO:39 wherein one or both of the sequences set forth in SEQ ID NOS: 37 and 39 has one unspecified amino acid substitution at any position therein. According to paragraph 7 of the declaration of Dr. Bergounioux (3/29/2005), the tobacco CKI, NtKIS1a, comprises a first sequence motif which is identical to the sequence set forth in SEQ ID NO:34, a second sequence motif comparable but not identical to the consensus sequence set forth in SEQ ID NO:35 (the second amino acid of SEQ ID NO:35, L, substituted with S in the tobacco CKI NtKIS1a), and a third sequence motif comparable but not identical to the consensus sequence set forth in SEQ ID NO:36 (the last amino acid of SEQ ID NO:36, E, substituted with Q in the tobacco CKI NtKIS1a).

The Examiner also maintains that the variation described in the consensus sequences set forth in Table 2 does not support the description of the plant CKIs recited in the claims because the nine CKIs on which the consensus sequences are based do not comprise the consensus sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ

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ID NO:36 wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein, and because the nine CKIs on which the consensus sequences are based do not further comprise the consensus sequences set forth in SEQ ID NO:37, SEQ ID NO:38, and SEQ ID NO:39 wherein one or both of the sequences set forth in SEQ ID NOS: 37 and 39 has one unspecified amino acid substitution at any position therein. The nine CKIs on which the consensus sequences are based vary with respect to certain amino acid residues at certain positions.

Applicants also point to *Capon v. Eshhar*, 418 F.3d 1349, 76 USPQ 1078 (Fed. Cir. 2005), and maintain that as in this case, the Examiner here has not considered the generic concept that Applicants of the present application have described, i.e., the concept of identifying and using a plant CKI in order to affect various phenotypic traits in plants. Also as in *Capon v. Eshhar*, Applicants maintain that the record in the present application does not show this concept to be in the prior art, and includes experimental verification as well as potential variability in the concept (provided by the specification, previously submitted declarations, and post-filing date publications). (reply pages 31-32)

The Examiner maintains that the generic concept of the present application has been considered, as well as potential variability in the concept. The point of disagreement is not with respect to the generic concept, or with respect to the potential variability in the concept. The point of disagreement with respect to whether or to what extent the limitations recited in the rejected claims are supported by Applicant's disclosure.

Last, Applicants point out that while it is necessary that an applicant for a patent give to the public a complete and adequate disclosure in return for the patent grant, the certainty required of the disclosure is not greater than that which is reasonable, having due regard to the subject matter involved, and Applicants maintain that the Examiner is demanding a certainty of disclosure which is unreasonable, having due regard to the subject matter involved, and when the specification and the record is considered as a whole. (reply pages 32-33)

The Examiner maintains that a certainty of disclosure which is unreasonable, having due regard to the subject matter involved, and when the specification and the record is considered as a whole, is not demanded. Having due regard to the subject matter involved, and when the specification and the record is considered as a whole, the disclosed species are not representative of the claimed genus, wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein, and wherein one or both of the sequences set forth in SEQ ID NOS: 37 and 39 has one unspecified amino acid substitution at any position therein. Having due regard to the subject matter involved, and when the specification and the record is considered as a whole, CKIs comprising the consensus sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 wherein one or more of the sequences set forth in SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36 has one unspecified amino acid substitution at any position therein do not find support in the specification as filed and thus constitute new matter, and CKIs further comprising the consensus sequences set forth in SEQ ID NO:37, SEQ ID NO:38, and SEQ ID NO:39 wherein one or both of the sequences set forth in SEQ ID NOS: 37 and

39 has one unspecified amino acid substitution at any position therein do not find support in the specification as filed and thus constitute new matter.

Double Patenting

Claim 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50, 52-57 and 60-92 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,710,227, issued March 23, 2004 from U.S. Application No. 09/526,597, for reasons of record.

The Office acknowledges Applicant's statement filed November 19, 2003 in response to the prior provisional rejection of claims 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50 and 52-57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9, 13-19, 21-23, 43-48 and 51-52 of copending Application No. 09/526,597, now U.S. Patent No. 6,710,227, submitting that a terminal disclaimer will be submitted upon allowance of the claims presently under consideration in this application.

Claim 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50, 52-57 and 60-92 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-9 and 13-23 of copending Application No. 10/688,291, for reasons of record.

The Office acknowledges Applicant's statement filed March 29, 2005 submitting that upon allowance of the claims under consideration in this application, an appropriate action will be taken in order to obviate the provisional double patenting rejection.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC



4/17/06